UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

GIANT EAGLE, INC.,	)	**Case No. 1:10 CV 1197**
	)	
Plaintiff,	)	**Judge Dan Aaron Polster**
	)	
vs.	)	**MEMORANDUM OF OPINION**
	)	
CEPHALON, INC., et al.,	)	**and**
	)	
Defendants.	)	**ORDER OF TRANSFER**

Pending before the Court are the following fully briefed motions: Defendant Cephalon, Inc.'s Motion to Transfer (**Doc #: 17**), and the Generic Defendants' Motion to Transfer Venue (**Doc #: 20**) (collectively, "the Transfer Motions"). Defendants ask the Court to transfer this case to the Eastern District of Pennsylvania where earlier-filed, related and now-consolidated cases are pending. The primary question in this case is whether certain agreements entered between the defendants (drug and generic drug manufacturers), which have an anti-competitive effect on competitors, violate federal and state antitrust laws. Because this is the primary question at issue in the Pennsylvania cases and for other reasons explained below, the Court **GRANTS** the Transfer Motions and **ORDERS** transfer of this case to the Eastern District of Pennsylvania.

I.

Plaintiff Giant Eagle, Inc. is engaged in the retail supermarket and pharmacy business. Defendant Cephalon, Inc. is a biopharmaceutical manufacturer. Defendants Teva

Pharmaceuticals USA, Inc. and its parent Teva Pharmaceutical Indus., Ltd. (together, "Teva"), Mylan Pharmaceuticals, Inc., Barr Laboratories, Inc., and Ranbaxy Laboratories Ltd. and its subsidiary Ranbaxy Pharmaceuticals, Inc. (together, "Ranbaxy") are generic drug manufacturers (collectively, the "Generic Defendants") .

Cephalon owns, by assignment, U.S. Patent No. RE37,516 (the "'516 Patent"), a particle size composition patent for modafinil, the active ingredient in PROVIGIL®. The '516 Patent expires on October 6, 2014, with pediatric exclusivity effectively extending the patent life to April 6, 2015.

On December 24, 1998, the FDA approved Cephalon's New Drug Application ("NDA") to market Provigil as a safe and effective treatment for excessive daytime sleepiness associated with narcolepsy, and Cephalon began marketing Provigil shortly thereafter. The FDA recognized modafinil as a "new chemical entity" under the Hatch-Waxman Act, extending the original date that generic drug manufacturers could file Abbreviated New Drug Applications ("ANDA") to December 24, 2002. See 21 U.S.C. § 355(j)(5)(F)(ii).

While drug manufacturers filing NDAs are required to provide comprehensive efficacy and safety studies, the Hatch-Waxman Act was designed to allow generic drug manufacturers to bypass those studies when filing an ANDA. An ANDA requires only that the applicant prove that the new generic drug is the bioequivalent of a brand name drug on the market. Id. §§ 355(j)(2)(A); (j)(2)(F); (j)(8)(B). Generic drug manufacturers must select one of four paragraphs under which to submit their ANDAs. Id. § 355(j)(2)(A)(vii). If the manufacturer submits its ANDA under "Paragraph IV" (certifying "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is

submitted), it must provide notice to the patent owner affected by the application. Id. § 355(b)(2)(B)(3). The filing of a "Paragraph IV" ANDA constitutes a technical patent infringement. *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 702 F.Supp.2d 514, 520 (E.D. Pa. 2010) ("*King Drug Co.*"). As such, the patent holder may sue the generic manufacturer for infringement within 45 days of receiving notice. 21 U.S.C. § 355(c)(3)(C). If the patent holder files such suit, approval of the ANDA is automatically stayed for 30 months, or until a district court issues a final decision holding that the patent has not been infringed or is otherwise invalid. Id. If the patent holder does not file suit within the allotted time, the FDA can approve the ANDA without delay. Id.

In order to provide generic drug manufacturers with an incentive to incur the risk of a potential infringement suit under Paragraph IV, the first ANDA filer maintains a 180-day exclusivity period. Id. § 355(j)(5)(B)(iv). That means that the FDA cannot approve a subsequent generic manufacturer's ANDA until 180 days after the earlier of (1) the date the first ANDA filer markets its generic equivalent; or (2) the date a district court decides that the patent is invalid or not infringed. Id. § 355(j)(5)(B)(iii).

On December 24, 2002, the Generic Defendants filed "Paragraph IV" ANDAs for approval to manufacture and market generic modafinil. All four were deemed to be "first-filers" entitled to 180-day exclusivity rights. If the FDA had approved the ANDAs, the Generic Defendants could have launched generic modafinil as early as 2006, and subsequent ANDA competitors could have launched their generic equivalents 180 days later. The manufacture and sale of generic modafinil would have driven down the price of modafinil for direct and indirect purchasers and the consuming public.

In response to the "Paragraph IV" ANDAs, Cephalon brought a patent infringement case against the Generic Defendants on March 28, 2003 in the District of New Jersey. *Cephalon, Inc. v. Mylan Pharmaceuticals, et al.*, D.N.J. Case No. 2:03-cv-1394-JCL-MF. The Generic Defendants filed answers challenging the validity of Cephalon's patent. By February 1, 2006, Cephalon reached separate settlement agreements with each of the Generic Defendants wherein the Generic Defendants agreed not to market generic versions of Provigil until April 6, 2012 in exchange for monetary compensation totaling $200 million in the form of licensing agreements, supply agreements, and/or research and development deals (the "Settlement Agreements").[1] Because the Generic Defendants did not prosecute their cases to final judgment and they have agreed not to market generic modafinil until April 6, 2012, the Settlement Agreements (sometimes referred to as "reverse payment agreements") effectively prevent subsequent generic applicants from obtaining FDA approval and marketing generic modafinil until late 2012. *See Apotex, Inc. v. Cephalon, Inc., et al*., E.D. Pa. Case No. 2:06-cv-2768-MSG, ECF No. 1 ¶¶ 68-71.

* * *

Beginning in 2006, the Settlement Agreements giving rise to this case spawned sixteen separate cases, some of which are class actions, all of which were filed in, or transferred to, the United States District Court for the Eastern District of Pennsylvania. The direct and indirect purchaser cases were consolidated into *King Drug Co. of Florence, Inc., et al. v. Cephalon, Inc., et al.*, E.D. Pa. Case No. 2:06-cv-1797-MSG. The end payor cases were consolidated into *Vista*

[1]Teva settled with Cephalon on December 8, 2005; Ranbaxy settled with Cephalon on December 22, 2005; Mylan settled with Cephalon on January 9, 2006; and Barr settled with Cephalon on February 1, 2006. *See generally King Drug Co.*, 702 F.Supp.2d at 522-23 (detailing the various terms of the four Settlement Agreements)

Healthplan, Inc., et al. v. Cephalon, Inc., et al., E.D. Pa. Case No. 2:06-cv-1833-MSG. A generic drug manufacturer that filed a subsequent, now-stalled, "Paragraph IV" ANDA to market generic modafinil filed its antitrust case in the Eastern District of Pennsylvania. *Apotex, Inc. v. Cephalon, Inc., et al*., E.D. Pa. Case No. 2:06-cv-2768-MSG. The Federal Trade Commission ("FTC") sued Cephalon regarding the Settlement Agreements in the Washington, D.C. district court, after which that court granted Cephalon's motion to transfer the case to the Eastern District of Pennsyhlvania (E.D. Pa. Case No. 2:08-cv-2141-MSG). *See Federal Trade Comm'n v. Cephalon, Inc.*, 551 F.Supp.2d 21 (D.D.C. 2008). More recently, a Tennessee district court transferred a case involving the same defendants, the same Settlement Agreements, and the same issues to the Eastern District of Pennsylvania. (See *Jabo's Pharmacy, Inc. v. Cephalon, Inc.*, E.D. Tenn. Case No. 2:09-CV-289, Doc #: 42, issued on September 27, 2010.) These consolidated Pennsylvania district court cases are euphemistically referred to as the *In re Modafinil* litigation. *See King Drug Co.*, 702 F.Supp.2d at 518. All the *In re Modafinil* cases arise from the same Settlement Agreements; they all allege that the Agreements constitute unlawful restraints of trade under federal and state antitrust laws; and the defendants in all cases are Cephalon and the Generic Defendants (except for the FTC case which brings its Sherman Antitrust Act claims against Cephalon alone).

In light of the coordinated proceedings taking place in the Eastern District of Pennsylvania, Cephalon and the Generic Defendants ask the Court to transfer this case to that district. The Court has reviewed the Motions (Doc ##: 17, 20), the omnibus opposition briefs (Doc ##: 26, 31) and the reply briefs (Doc ##: 28, 29, 34) and is prepared to issue its ruling.

II.

The governing statute, 28 U.S.C. § 1404(a), provides that, "[f]or the convenience of parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought." The district court has broad discretion over whether to transfer a case under this section. *Phelps v. McClellan*, 30 F.3d 658, 663 (6th Cir. 1994).

Deciding a motion to transfer venue requires a case-by-case consideration of convenience of the parties and witnesses, public-interest factors of systemic integrity, and general principles of fairness. *Stewart Org., Inc. v. Ricoh Corp.*, 487 U.S. 22, 29 (1988) (citing *Van Dusen v. Barrack*, 376 U.S. 612, 622 (1964)). "No one factor is dispositive; transfer is appropriate if the balance of these factors 'strongly' favors trying it in the transferee district." *Donia v. Sears Holding Corp.*, No. 1:07cv2627, 2008 WL 2323533, at *2 (quoting *Picker Int'l, Inc. v. Travelers Indem. Co.*, 35 F.Supp.2d 570, 573 (N.D. Ohio 1998)). The party seeking transfer under § 1404(a) bears the burden of establishing that the balance of relevant factors weighs strongly in favor of transfer. *Levy v. Cain, Watters & Assoc., PLLC*, No. 2:09cv723, 2010 WL 271300, at *9 (S.D. Ohio Jan. 15, 2010) (citations omitted).

III.

The Ohio filing of this case by Giant Eagle, a Pennsylvania corporation headquartered in Pennsylvania, while sixteen cases challenging the same Settlement Agreements and alleging the same antitrust claims are undergoing coordinated discovery in the Eastern District of Pennsylvania, gives this Court pause. Giant Eagle obviously does not dispute that this case

could have been brought in the Eastern District of Pennsylvania. It does, however, dispute that the other factors weigh strongly in favor of transfer there.

The central issue in this case – and the central issue before the Pennsylvania court – is whether Defendants committed any antitrust violations in connection with their settlement of the *Cephalon* patent infringement cases. The Court has reviewed the *In re Modafinil* complaints filed in the Pennsylvania district court and, except for the parties' names and a state law claim, the Giant Eagle complaint mirrors verbatim the factual allegations and claims asserted in the *In re Modafinil* complaints filed by the direct and indirect Provigil purchasers.

Notably, two months before Giant Eagle filed this case in Ohio, the Pennsylvania court issued an opinion denying an omnibus motion, filed by Cephalon and the Generic Defendants, to dismiss the same federal antitrust claims that are alleged in the instant case. *King Drug Co.*, 702 F.Supp.2d 514. The Pennsylvania court also rejected the Defendants' challenge to the direct purchasers' standing to bring those claims, and denied their request to dismiss the state antitrust claims that were not dismissed by stipulation of the parties. It is an open question whether the rulings in that district court have a preclusive effect on this Court's rulings. This factor alone shows why it is in everyone's interest that the related cases be litigated in Pennsylvania, the home of Giant Eagle. Transfer is imperative to avoid the risk of inconsistent rulings, not to mention the obvious waste of private and public resources.

In fact, Giant Eagle does not want its case to be transferred to Pennsylvania because it expects this Court to treat its Ohio Valentine Act claim differently than it will be treated in Pennsylvania. (See Doc #:). As articulated by Giant Eagle:

> Although the Third Circuit has not yet reached the relevant issues, the Court in the Eastern District of Pennsylvania has indicated that it will apply a "scope of the

> patent framework" for adjudicating the legality of the Defendants' reverse payment agreements. *King Drug Co. of Florence, Inc. v. Cephalon, Inc*., 2010 WL 1221793 at *11-12 (E.D. Pa. 2010). In contrast, Giant Eagle's Valentine Act claim should be adjudged in accordance with Sixth Circuit precedent. . . . As noted in Giant Eagle's Opposition Brief, the Sixth Circuit Court of Appeals has conclusively determined that an agreement similar to those present here was "a classic example of a *per se* illegal restraint of trade." *Cardizem CD Antitrust Litig*., 332 F.3d 896 (6th Cir. 2003), *cert. denied sub nom., Andrx Pharms., Inc. v. Kroger Co.*, 543 U.S. 939 (2004). *See also King Drug*, 2010 WL 1221793 at **8, 11-12 (recognizing Sixth Circuit precedent as established in *Cardizem*, but refusing to apply *Cardizem's per se* standard).

(Doc #: 30-1, at 3-4.)

In *Cardizem*, the Sixth Circuit found a reverse payment agreement entered between a drug manufacturer and its generic competitor to be *per se* illegal. That agreement was an interim agreement in which a drug manufacturer agreed to pay a generic manufacturer, which had filed a Paragraph IV ANDA, not to market its generic equivalent should it receive approval from the FDA to do so. Such approval necessarily required a finding that the generic equivalent did not infringe the name brand manufacturer's patent. After the FDA approved the ANDA application, the drug manufacturer paid the generic manufacturer the agreed $10 million per quarter to refrain from marketing the approved generic equivalent. It was the payment to the only competitor on the market to refrain from selling its approved generic equivalent that the Sixth Circuit found "undisputed and dispositive" when concluding that the agreement was *per se* illegal. *Cardizem*, 332 F.3d at 907.

The *Cardizem* agreement is distinguishable from the Settlement Agreements in this case, where the FDA has not ruled on the Generic Defendants' ANDA applications or the validity of the '516 patent. Because the Generic Defendants have not received final FDA approval to manufacture their Provigil equivalents, it is uncertain whether the Sixth Circuit would consider

the Settlement Agreements herein a *per se* violation, or whether this Court would be constrained to follow *Cardizem* given the distinguishing facts. Since the facts of this case are more analogous to cases in other circuits where the "scope of patent framework" has been applied, this Court might be inclined to apply that framework as well. And given the fact that the Third Circuit has not addressed the framework for analyzing reverse payment agreements previously, there is no telling how the Third Circuit would rule on this issue on appeal. In any event, any court addressing the Ohio Valentine Act claim must apply the same framework it applies to the Sherman Act claims. *See, e.g., Johnson v. Microsoft Corp.*, 106 Ohio St.3d 278, 281 (2005) ("[T]he Ohio General Assembly patterned Ohio's antitrust provisions in accordance with federal antitrust provisions" and "as a consequence this court has interpreted the statutory language in light of federal judicial construction."); *Nilavar v. Mercy Health Sys.-Western Ohio*, 244 Fed. Appx. 690, 694 n.3 (6th Cir. 2007) ("The Valentine Act was modeled after the Sherman Act and federal law applies to its interpretation."). More importantly, the law is clear that the risk of inconsistent rulings is a factor strongly favoring transfer to the court where earlier-filed, related cases are pending. Giant Eagle is free to raise any issues it desires in the transferee court, and the transferee court is perfectly capable of addressing those issues.

Giant Eagle argues that its case should be litigated in Ohio because it has been injured by the unlawful anti-competitive effects of the Settlement Agreements on its significant pharmaceutical business here.[2] In fact, Giant Eagle has suffered the same injury in Pennsylvania (not to mention West Virginia and Maryland where Giant Eagle in-stores pharmacies are also

[2]Giant Eagle asserts that it has subsidiaries in Ohio and Delaware, and that it has 123 supermarkets (including 112 pharmacies) located in Ohio and over 17,000 employees residing in Ohio. However, the subsidiaries are not plaintiffs in this case, and it is the location of Giant Eagle's incorporation and principal place of business that must be taken into consideration here.

located). In any event, the question of whether, and if so how much, damage Giant Eagle has suffered due to the Settlement Agreements is secondary to the question whether there is an antitrust violation in the first place. And the question of how much damage Giant Eagle has suffered in Ohio is secondary to the question of how much damage Giant Eagle has suffered across the country. As such, the Court is in agreement with the District of Columbia which examined this exact issue and transferred its case to Pennsylvania because the "negotiations that led to the settlement agreements" form "the heart of this controversy." *Federal Trade Comm'n*, 702 F.Supp.2d at 29.

To be sure, Giant Eagle's Pittsburgh headquarters is closer to Cleveland than Philadelphia. Thus, the Northern District of Ohio is a more convenient forum for Giant Eagle, and the two witnesses it has identified (both of whom live in the Western District of Pennsylvania), to travel. However, Giant Eagle is a Pennsylvania corporation – and requiring all Defendants for whom the Eastern District of Pennsylvania is more convenient to travel to Cleveland to re-litigate the same claims involving the same facts that arose in the Eastern District of Pennsylvania and are the subject of coordinated proceedings well underway in that district, is entirely unreasonable given the private and public interest in the efficient use of litigation and judicial resources and the avoidance of competing rulings. *See, e.g., Donia*, 2008 WL 2323533, at *4 n.2 (the "pendency of a similar action in the transferee court is a universally recognized reason for granting a venue change") (internal quotation marks omitted).

Affording the plaintiff's chosen forum substantial deference does not apply when, as here, the plaintiff selects a forum with no meaningful ties to the events giving rise to the case. None of the negotiations that led to the Settlement Agreements at the heart of this case took

place in, or were in any way related to, Ohio. None of the documents or witnesses involved in negotiating the Settlement Agreements reside in Ohio. The location of the patent infringement suits which resulted in the Settlement Agreements is unrelated to Ohio. And none of the parties, including Giant Eagle, is incorporated or maintains its principal place of business in Ohio. *See Federal Trade Comm'n*, 551 F.Supp.2d at 26 (transferring that case to the Eastern District of Pennsylvania because "neither the operative events of this lawsuit nor the parties that were involved in those events have any meaningful connection to the District [of Columbia]." *See also JFE Steel Corp. v. ICI Americas*, Inc., No. 1:06cv2386, 2008 WL 4449080, at *1 (N.D. Ohio Sep. 30, 2008) ("[W]here the chosen forum has no relation to the parties, cause of action, or location of evidence (including witnesses), plaintiff's choice becomes just one of the many factors to be weighed equally with other relevant factors."); *Knight v. Horace Mann Ins. Co.*, No. 1:07cv3772, 2007 WL 4562316, at *2 (N.D. Ohio Dec. 21, 2007) ("While a plaintiff's choice of forum is generally entitled to substantial weight, that choice is given less consideration if the operative events giving rise to the lawsuit took place in a forum other than that chosen by the plaintiff.") (citations omitted).

Finally, following the Pennsylvania court's issuance of the *King Drug Co.* decision, the court issued a schedule for coordinated discovery in the *In re Modafinil* cases. (See *King Drug Co.*, E.D. Pa. Case No. 2:06-cv-1797-MSG, Doc #: 280.) The fact discovery cutoff is February 11, 2011, the expert discovery cutoff is May 27, 2011, and the deadline for filing dispositive motions is June 17, 2011. (Id.) A trial date has not yet been selected. (Id.) The Pennsylvania court held a global settlement conference on June 18, 2010 which appears to have failed due to the lack of discovery. (See id., Doc #: 307.) Counsel are scheduled to meet with the

Pennsylvania district judge in November to determine when it would be appropriate for settlement discussions to reconvene. (Id.) Transfer of this case to the Eastern District of Pennsylvania and consolidation with the *In re Modafinil* cases would actually accelerate litigation of this case (in which responsive pleadings or 12(b)(6) motions have not yet been filed, pretrial proceedings have not been scheduled, and discovery has not yet commenced) by bringing it into lockstep with the Pennsylvania cases, thus conserving the parties' resources.

In summary, the Court finds that the locus of operative facts, the lack of meaningful ties to Ohio, the convenience of all the parties and most of the witnesses, the Pennsylvania court's longstanding familiarity with the claims and issues presented in the Giant Eagle complaint, the private interest in avoiding the duplication of litigation resources and inconsistent judgments, and the public's interest in the efficient use of judicial resources all weigh heavily in favor of transfer of this case to the Eastern District of Pennsylvania, the state of Giant Eagle's incorporation and headquarters.

IV.

Because the Court finds that the balance of factors weighs heavily in favor of transfer, the Court hereby **GRANTS** the Transfer Motions (**Doc ##: 17 and 20**). The Clerk of Court is hereby directed to **TRANSFER** this case to the Eastern District of Pennsylvania, where numerous related cases are presently pending.

IT IS SO ORDERED.

/s/ Dan A. Polster September 30, 2010
Dan Aaron Polster
United States District Judge